8-23-99

014083

DATA EVALUATION RECORD

PROHEXADIONE CALCIUM
(BAS 125 08 W)

Study Type: §81-2; Acute Dermal Toxicity

Work Assignment No. 1-02-25CC (MRID 44457737)

Prepared for
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Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

For AK Mlopl 8/23/99

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For SD Mlopl 8/23/99

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat
OPPTS Number:, 870.1200 OPP Guideline Number: §81-2

DP BARCODE: D246707 SUBMISSION CODE: S543930
P.C. CODE: 112600 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): Prohexadione calcium (74.9% purity)

SYNONYMS: BAS 125 08 W; calcium salt of 3-oxido-4-propionyl-5-oxo-3-cyclohexene-carboxylate

CITATION: Poelloth, C. (1996) Study on the acute dermal toxicity of BAS 125 08 W in rats. BASF Aktiengesellschaft, Ludwigshafen/Rhine, Federal Republic of Germany. Laboratory Project Number 11A0242/951044. February 7, 1996. MRID 44457737. Unpublished.

SPONSOR: BASF Corporation, P.O. Box 13528, Research Triangle Park, NC.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 44457737), five young adult Wistar CHBB:THOM (SPF) rats/sex were dermally exposed to prohexadione calcium (74.9% purity) at 2,000 mg/kg (limit dose) for 24 hours. The test substance was applied as a 50% concentration in distilled water to >10% of the total body surface area. Animals were observed for clinical signs of toxicity and mortality for up to 14 days postdosing.

Dermal LD_{50} Males = >2,000 mg/kg (observed)
Females = >2,000 mg/kg (observed)

Prohexadione calcium is classified as **TOXICITY CATEGORY III** based on the observed LD_{50} values for both sexes.

All animals survived and appeared normal during the 14-day observation period. Very slight erythema was observed at 3/10 sites 30-60 minutes following patch removal (day 1) and subsided by 7 days (the next observation). No significant treatment-related effect on body weight was observed in males. In contrast, 3/5 females lost weight between 0 and 7 days, and exhibited only

slight overall gains, ranging from 0.89 to 4.5%. Necropsy after 14 days revealed no observable abnormalities

This study is classified **acceptable (§81-2)** and satisfies the guideline requirement for an acute dermal study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: Prohexadione calcium (BAS 125 08 W)
   Description: Light brown granules
   Lot/Batch #: AF 284-79
   Purity: 74.9%
   CAS #: 127277-53-6

2. Vehicle: Distilled water

3. Test animals: Species: Rat, albino
   Strain: Wistar, CHBB:THOM (SPF)
   Age: Young adult
   Weight: 255-266 g males; 215-224 g females
   Source: Dr. K. Thomae GMBH, Biberach, Federal Republic of Germany
   Acclimation period: ≥1 Week
   Diet: Kliba-Labordiaet 343, Klingetalmuehle AG Keiseraugst, Switzerland, ad libitum
   Water: Tap water, ad libitum
   Housing: One animal/cage in stainless steel wire mesh cages
   Environmental conditions:
   Temperature: 20-24 °C
   Relative humidity: 30-70%
   Air changes: Not specified
   Light: 12-Hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: August 3-17, 1995

2. Animal assignment and treatment: Fur from the dorsal and dorsolateral regions of the trunk of five young adult Wistar CHBB:THOM (SPF) rats/sex was clipped at least 15 hours prior to dermal administration of prohexadione calcium at 2,000 mg/kg (limit

dose). To enhance dermal contact, the test material was mixed with distilled water (50% concentration, w:v) prior to application to the clipped skin; the actual size of the application area was approximately 50 cm^2 (>10% of the total body surface area). Each test site was covered with a 4-ply gauze patch secured with Fixomull stretch adhesive fleece. After 24 hours, the coverings were removed, and the application sites were washed with warm water. The rats were observed for signs of gross toxicity and/or mortality at "several times" on the day of dosing and at least once daily thereafter for up to 14 days. Dermal irritation was graded using the Draize scale on days 1 (30-60 minutes following patch removal), 7, and 14. Body weights were recorded at 0 (prior to dosing), 7, and 13 days. At 13 days, the surviving animals were fasted for at least 16 hours, then sacrificed, necropsied, and examined for gross pathological changes.

3. Statistics: Not applicable to this study.

II. RESULTS AND DISCUSSION:

A. Mortality: All animals survived the 14-day observation period.

Dermal LD_{50} Males = >2,000 mg/kg (observed)
Females = >2,000 mg/kg (observed)

B. Clinical observations: No signs of toxicity were observed.

Thirty to 60 minutes following patch removal (day 1), very slight erythema (score of 1) was observed at 1/5 male and 2/5 female sites. Irritation completely subsided by 7 days (the next observation).

C. Body Weight: No significant treatment-related effect on body weight was observed in male animals, who exhibited an overall (0-13 days) average increase of 17%. The body weights of 3/5 females decreased slightly between 0 and 7 days, then recovered by 14 days. All females exhibited slight overall gains, ranging from 0.89 to 4.5%.

D. Necropsy: Necropsy after 14 days revealed no observable abnormalities.

E. Deficiencies: There were no deficiencies that affected the results of this study.